- 23. (New) A substantially purified nucleic acid molecule having between 90% and 100% sequence identity with a nucleic acid molecule of SEQ ID NO: 1 or complement thereof.
- 24. (New) The substantially purified nucleic acid molecule of claim 24, wherein said substantially purified nucleic acid molecule has between 99% and 100% sequence identity with SEQ ID NO: 1 or complement thereof.



#### Remarks

#### 1. Support for the Amendments

Non-elected claims 8-19 have been canceled without prejudice to or disclaimer of the underlying subject matter. Claims 1-4 and 6 have been amended. Claims 20-24 have been added. Support for the foregoing claim amendments and new claims may be found throughout the specification and in the original claims, for example at page 10, lines 5-8, at page 15, line 17 through page 16, line 2, at page 1516, line 1 through page 1518, line 16, at page 1520, line 1 through page 1523, line 5, and at page 1526, line 1 through page 1527, line 3. No new matter enters by way of these amendments. Upon entry of the foregoing amendments, claims 1-7 and 20-24 are pending in the application.

The specification has been amended to remove embedded hyperlinks. No new matter enters by way of this amendment.

#### 2. The Restriction Requirement

Applicant acknowledges the finality of the restriction requirement but maintains his traversal. To facilitate prosecution, however, Applicant has removed the non-elected claims from the application.

Applicant also acknowledges the finality of the election requirement to a single nucleotide sequence, but maintains his traversal. Applicant respectfully disagrees that the polynucleotide sequences of the instant application would be considered of the complexity that merits restriction to a single sequence in contradiction to the expressed USPTO policy of examining ten sequences, as set forth in the Manual of Patent

Examining Procedure. (See MPEP, 8<sup>th</sup> ed., August 2001, Section 803.04, page 800-10). However, in order to facilitate prosecution Applicant has removed non-elected sequences from the claims.

#### 3. Rejection of Claims 1-7 under 35 U.S.C. § 101

Claims 1-7 were rejected under 35 U.S.C. § 101, for allegedly not being supported by either a specific, substantial and credible utility or a well-established utility. Office Action at page 3. Applicant respectfully traverses this rejection.

The Examiner argues that the because the specification discloses that SEQ ID NOS: 1-82359 encode proteins, are promoters, and are markers, the specification does not identify what SEQ ID NO: 1 is. Office Action, at page 3. This is not correct. The Examiner has identified a cursory summary of the invention, however, the specification further describes that the nucleic acid molecules of the present invention can be used as markers and further, a class of the nucleic acid molecules of the present invention comprise promoter or partial promoter regions (see, e.g., specification at page 1526, lines 1-5), and a class of agents of the present invention comprise one or more of the peptide molecules encoded by a nucleic acid molecule, complement of fragment thereof of the present invention (see, e.g., specification at page 1540, lines 16-23). One of ordinary skill in the art can discern from the specification and from the sequence listing the class of nucleotide sequences into which SEQ ID NO: 1 falls.

It is well established that "when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown." Raytheon Co. v. Roper Corp., 724 F.2d 951, 958, 220 U.S.P.Q. 592, 298 (Fed. Cir. 1983). The present specification describes many objectives that are met by the present invention. For example, the specification describes that the nucleic acid molecules of the present invention can be used as genetic markers, in physical mapping, to identify polymorphisms, and to monitor expression. See, e.g., specification beginning at page 1546, under the heading "Uses of the Agents of the Invention". However, the Examiner contends that none of these utilities constitute a "substantial" or "specific" utility. Applicant respectfully disagrees with this assertion.

Many of these uses are directly analogous to the use of a microscope. An important utility of a microscope resides in its use to identify and characterize the structure of biological tissues in a sample, cell or organism. Significantly, the utility of the microscope under 35 U.S.C. § 101 is not compromised by its use as a tool in this manner. Many of the presently disclosed utilities are directly analogous to the utilities of a microscope, *i.e.*, the claimed nucleic acid molecules may be used to identify and characterize other nucleic acid molecules within a sample, cell or organism. Such utility is indistinguishable from the legally sufficient utility of a microscope. Thus, the presently disclosed sequences possess the requisite utility under 35 U.S.C. § 101.

In view of the above, Applicant contends that the claimed nucleic acid molecules are supported by credible, specific and substantial utilities disclosed in the specification. Moreover, the Examiner has failed to raise any credible evidence challenging the presently asserted utilities. Consequently, the rejection of claims 1-7 under 35 U.S.C. § 101 is improper. Reconsideration and withdrawal of this rejection are respectfully requested.

## 4. The Rejection of Claims 1-7 Under 35 U.S.C. § 112, 1st Paragraph

In the Office Action, at page 4, the Examiner has rejected claims 1-7 as not being enabled by the specification, because the claimed invention allegedly lacks utility. Applicant respectfully traverses this rejection. This rejection is erroneous and has been overcome by the foregoing arguments regarding utility. Thus, the enablement rejection under 35 U.S.C. § 112, first paragraph is improper. Reconsideration and withdrawal are respectfully requested.

## 5. The Rejection of Claims 2-4 and 6-7 Under 35 U.S.C. § 112, 1st Paragraph

Claims 2-4 and 6-7 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which "was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession if the claimed invention." Office Action at

page 4. According to the Examiner, the elements claimed in claims 2, 3, 6 and 7 do not appear to be contained within SEQ ID NO: 1.

Although Applicant respectfully disagrees that the claimed subject matter is not adequately described in the specification as filed, the claims have been amended to facilitate prosecution. As such, the rejection under 35 U.S.C. § 112, first paragraph, has been rendered moot. Reconsideration and withdrawal of this rejection are respectfully requested.

#### 6. The Rejection of Claims 1-3 and 5-7 Under 35 U.S.C. § 112, Second Paragraph

Claims 1-3 and 5-7 were rejected under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite. Office Action at page 5. According to the Examiner, the phrase "specifically hybridizing" is not defined in the specification and "it cannot be determined what level of hybridization is required by the claims". *Id*.

Applicant respectfully disagrees. The phrase "specifically hybridizing" is defined at page 1516, lines 3-5, of the present specification. However, to facilitate prosecution, claim 1 has been amended to recite specification hybridization conditions. As such, reconsideration and withdrawal of this rejection are respectfully requested.

# 7. The Rejection of Claims 1 and 4 Under 35 U.S.C. § 102

The Examiner has rejected claims 1 and 4 under 35 U.S.C. § 102(a) as anticipated by Walbot. (Accession No. AI834598, February 2, 2000). Office Action at pages 5-6. Applicant respectfully disagrees.

The Examiner's position is based on the allegation that SEQ ID NO: 1 is not disclosed in Provisional Application No. 60/141,233. Office Action at page 6. As such, the Examiner contends no priority claim under 35 U.S.C. § 119 could be made in the present application. This position cannot be supported.

The Examiner has offered no evidence to contradict Applicant's claim of priority to Application. Ser. No. 60/141,233, filed June 29, 1999. Moreover, Applicant explicitly submits that SEQ ID NO: 1 is identical to SEQ ID NO: 1 of Provisional Application No.

60/141,233. A copy of the sequence alignment data is attached for the Examiner's convenience as Exhibit A. As such, Applicant has demonstrated possession of the claimed SEQ ID NO: 1 since at least June 29, 1999, prior to the reference date of February 2, 2000, for Accession No. AI834598.

Furthermore, even if Applicant were not entitled to the priority date of June 29, 1999, the cited reference still would not anticipate claims 1 and 4. For a prior art reference to anticipate in terms of 35 U.S.C. § 102, every element of the claimed invention must be identically shown in a single reference. *Diversitech Corp. v. Century Steps, Inc.*, 850 F.2d 675, 677, 7 U.S.P.Q. 2d 1315, 1317 (Fed. Cir. 1988). *See also Kalman v. Kimberly Clark Corp.*, 713 F.2d 760, 771 (Fed. Cir. 1983), *cert. denied*, 465 U.S. 1026 (1984). AI834598 does not teach every element of the claimed invention.

The Examiner alleges that AI834598 has "sequence in common with SEQ ID NO: 1." Office Action at page 6. However, the Examiner has given no indication of the extent of identity that AI834598 shares with SEQ ID NO: 1. No evidence, extrinsic or otherwise, has been presented by the Examiner in support of the proposition that AI834598 would necessarily hybridize to a complement of a fragment of SEQ ID NO: 1. Instead of providing evidence, the Examiner appears to shift the burden of proof to Applicant to provide evidence that the nucleic acids are not identical. This is not the law.

Furthermore, a rejection under 35 U.S.C. § 102(a) is only proper if, *inter alia*, an anticipatory reference is available publicly. The Examiner has submitted no evidence that AI834598 was available to the public prior to Applicant's filing date. The Examiner apparently relies on the date the nucleotide sequence was submitted to the GenBank database to establish the reference date under §102(a). However, there is no evidence that the sequence was published or otherwise available to the public.

In view of the above, Applicant contends the rejection under 35 U.S.C. § 102(a) is improper. Reconsideration and withdrawal of this rejection are respectfully requested.

#### Conclusion

In view of the above, the presently pending claims are believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections and pass the application to issue. The Examiner is encouraged to contact the undersigned with respect to any unresolved issues remaining in this application.

In the event that extensions of time beyond those petitioned for herewith are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned. Applicant does not believe that any fees in addition to those provided for in the accompanying documents, are due at this time. However, if any fees under 37 C.F.R. 1.16 or 1.17 are required in the present application, including any fees for extensions of time, then the Commissioner is hereby authorized to charge such fees to Deposit Account No. 50-2387, referencing docket number 16517.144.

Respectfully submitted,

Holly Logue Prutz (Reg. No. 47,755) David R. Marsh (Reg. No. 41,408)

Date: January 7, 2003

ARNOLD & PORTER 555 Twelfth Street, N.W. Washington, D.C. 20004-1206 (202) 942-5000 telephone (202) 942-5999 facsimile

#### Marked-Up Version of Amended Specification

At page 1, line 17 to page 2, line 4:

Sequence tagged connectors, or STCs, are sequences of insert data generated from both ends (at the vector-insert point) of a BAC clone in a genomic library. These sequences, and BACs containing these STC sequences, can be used, for example, for marker development, genetic mapping or linkage analysis, marker assisted breeding, and physical genome mapping (Venter, et al., Nature, 381:364-366 (1996), the entirety of which is herein incorporated by reference; Choi and Wing, [http://www.] www-genome.clemson.edu/protocols2-nj.html July, 1998). STCs can represent a copy of up to a full length of a mRNA transcript, a promoter element or part of a promoter, can contain simple sequence repeats (also called microsatellites) repetitive elements or fragments of repetitive elements, other DNA markers, or any combination thereof.

#### At page 5, lines 6 through 15:

Similarity analysis includes database search and alignment. Examples of public databases include the DNA Database of Japan (DDBJ) [(http://www.ddbj.nig.ac.jp/)] Genebank [(http://www.ncbi.nlm.nih.gov/web/Genbank (www-ddbj.nig.ac.jp/); /Index. htlm)] (www-ddbj.nig.ac.jp/); and the European Molecular Biology Laboratory Database (EMBL) [(http://www.ebi.ac.uk/ebi\_ Nucleic Acid Sequence docs/embl db.html)] (www-ddbj.nig.ac.jp/). A number of different search algorithms have been developed, one example of which are the suite of programs referred to as BLAST programs. There are five implementations of BLAST, three designed for nucleotide sequences queries (BLASTN, BLASTX, and TBLASTX) and two designed for protein sequence queries (BLASTP and TBLASTN) (Coulson, Trends in Biotechnology, 12:76-80 (1994); Birren, et al., Genome Analysis, 1:543-559 (1997)).

### Marked-Up Version of Amended Claims

- 1. (Once amended) A substantially purified nucleic acid molecule, said nucleic acid molecule capable of specifically hybridizing <u>under conditions of 6.0 X sodium chloride/ sodium citrate (SSC) at about 45°C, followed by a wash of 2.0 X SSC at 50°C to a second nucleic acid molecule having a nucleic acid sequence [selected from the group consisting] of SEQ ID NO: 1 [through SEQ ID NO: 82359] or a complement thereof [or fragment of either].</u>
- 2. (Amended) The substantially purified nucleic acid molecule according to claim 1, wherein said nucleic acid molecule <u>further</u> comprises a microsatellite sequence.
- 3. (Amended) The substantially purified nucleic acid molecule according to claim 1, wherein said nucleic acid molecule <u>further</u> comprises a region having a single nucleotide polymorphism.
- 4. (Amended) The substantially purified nucleic acid molecule according to claim 1, wherein said nucleic acid molecule comprises a nucleic acid molecule having a nucleic acid sequence [selected from the group consisting] of SEQ ID NO: 1 [through SEQ ID NO: 82359] or a complement thereof [or fragment of either].
- 6. (Amended) The substantially purified nucleic acid molecule according to claim 1, wherein said nucleic acid molecule **[has]** further comprises a promoter or partial promoter region.